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10/552,543	08/30/2006	Robert J. Watts	35938-505N01US	4332

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EXAMINER	
ROBINSON, JAMES MARSHALL	

ART UNIT	PAPER NUMBER
3772	

MAIL DATE	DELIVERY MODE
10/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,543	WATTS, ROBERT J.	
	Examiner	Art Unit	
	James M. Robinson	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19,20,22-25 and 27-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,20,22-25 and 27-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/13/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to amendments/arguments filed 8/13/2009. Currently claims 19-20, 22-25 and 27-41 are pending; claims 19, 30, 33, 37 and 38 have been amended amended. New claims 40 and 41 have been added.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/13/2009 has been entered.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 19, 20, 23-25 and 27-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Philipp (US 4559934) in view of Einarsson et al. (US 6,592,539).

Regarding claim 19, Philipp discloses an ankle-foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising a compression stocking (1)

formed of contiguous first and second tubular members (fig. 1), said second tubular member being set at an angle to the first tubular member to define, at least in use, a generally L-shaped cavity configured to accept and fit closely about the foot and ankle (fig. 1) of the patient; and a rib (7) attached to (col. 4, lines 42-44) a region of the compression stocking which overlies the dorsum (col. 2, lines 30-35) of the patient's foot in use, the rib having a resilience that is appropriate for resisting the particular degree of plantarflexion experienced by the patient.

Although Philipp discloses the rib is made of an elastically yielding material, such as a plastic or steel (col. 4, lines 39-42), Philipp fails to disclose the rib is composed of a silicone elastomer.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize an elastically yielding material such as silicone elastomer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Further, utilization of a rib composed of silicone elastomer in order to stiffen or reinforce a support garment is a well known quality known to one skill in the art, as evidenced by US patent 6,109,267 to Shaw et al. (see col. 5, lines 35-49).

Philipp fails to disclose the rib is bonded to a region of the compression stocking.

However Einarsson discloses an orthotic tubular sleeve including a portion coated with silicone elasotmer bonded to the fabric material of the sleeve (col 1 ln 45-50) that is cured (col 4 ln 25-33).

It would have been obvious to one of ordinary skill in the art at the time of the invention to integrate the rib of the Philipp device by the known technique of bonding as taught by Einarsson in order to allow an alternative form of permanent attachment of the rib to the compression stocking.

Further, the recitation -- said rib obtained by applying a silicone elstomer to the compression stocking so that the elastomer impregnates at least a portion of the compression stocking and forms, when cured, a bond between the rib and the compression stocking -- is treated as a product by process limitation. The determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985).A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art.

Regarding claim 20, Philipp discloses an orthosis wherein the compression stocking is operable to exert a compressive force on said foot and ankle of said patient (col. 4, lines 24-25).

Regarding claim 23, Philipp discloses an orthosis wherein the compressive force is more or less than at least 5 mm Hg (approximately 670 Pascals)

Regarding claim 24, Philipp discloses an orthosis wherein different regions of the compression stocking exert different compressive forces on the foot and ankle of the

patient (4, 15, reinforced areas of the orthosis create different compressive forces on the foot and ankle of the patient).

Regarding claim 25, Philipp discloses an orthosis wherein a second tubular member exerts a greater compressive force on the foot (4) than the compressive force exerted on the ankle by the first tubular member (col. 3, lines 12-14).

Regarding claim 27, Philipp discloses a resilient rib (7) permanently secured to an orthosis.

Philipp fails to disclose the resilience of the rib may be varied by varying the thickness of the rib.

It would have been obvious to one having ordinary skill in the art at the time the invention was made that rib resiliency is correlated to the thickness of the rib since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 28, Philipp discloses an orthosis wherein the resilience of the rib (7), as between a first orthosis and a second orthosis, may be varied by varying the composition of the rib of one orthosis as compared to the other (col. 4, lines 39-42; Philipp discloses that the plate made of an elastically yielding material, for example, a plastic or steel, this range of materials would inherently vary the resilience of the rib/plate).

Regarding claims 29 and 39, Philipp substantially discloses the invention as claimed; see rejection to claim 19. However Philipp does not explicitly teach the rib is of 35 to 80 shore silicone elastomer. It would have been obvious to one having ordinary

skill in the art at the time the invention was made to optimize the measure of the shore hardness of the silicone by varying the composition of elastomer, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claim 30, Philipp discloses an orthosis wherein a rib comprises a pair of proximal wings (18) extending from the rib around either side of the ankle of the patient towards the back of the ankle of the patient (fig. 3), said wings terminating at the back of the ankle (note: "back of the ankle" is not an anatomical distinction and dependent on one's perspective) and defining a gap between a terminal end of each wing.

Regarding claim 31, Philipp discloses an orthosis wherein proximal wings (18) extend in parallel to a proximal edge of the elastic structure (fig. 1).

Regarding claim 32, Philipp discloses an orthosis wherein the proximal wings (18) have the same resilience or a different resilience to that of the rib (the proximal wings are made of the same material as the rest of the plate, therefore inherently have the same resilience as the rest of the plate).

Regarding claim 33, Philipp discloses an orthosis wherein a rib comprises a pair of distal wings (17) extending from the rib (7), in the region of the metatarsal heads, towards the plantar aspect of the foot (fig. 1) and defining a gap between the terminal end of each wing.

Philipp is silent to the pair of distal wings extending from the rib around and partly underneath the foot and terminating underneath the foot.

Philipp discloses the claimed invention except for the pair of distal wings extending from the rib around and partly underneath the foot and terminating underneath the foot. It would have been an obvious matter of design choice to design the wing in the manner stated above, since applicant has not disclosed that the portion of the wing being partly underneath the foot solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the distal wing design of Philipp.

Regarding claim 34, Philipp discloses an orthosis wherein distal wings (17) extend generally in parallel to a distal edge of the compression stocking (fig. 1).

Regarding claim 35, Philipp discloses an orthosis wherein distal wings (17) have the same resilience or a different resilience to that of the rib (the distal wings are made of the same material as the rest of the plate, therefore inherently have the same resilience as the rest of the plate).

Regarding claim 36, Philipp discloses an orthosis wherein a rib (7) comprises a pair of proximal wings (18) extending from the rib towards the back of the ankle of the patient, and further comprises a pair of distal wings (17) extending from the rib, in the region of the metatarsal heads, towards the plantar aspect of the foot

Regarding claim 37, the method of manufacture of the device of Philipp in incorporates the claimed method steps including:

providing compression stocking formed of contiguous first and second tubular members set at an angle to one another to define, at least in use, a generally L-shaped cavity configured to accept and fit closely about the foot and ankle of a patient; mounting the compression stocking on a foot-shaped anvil ; preparing a silicone elastomer having a resilience which is appropriate for resisting the particular degree of plantarflexion experienced by the patient; applying the rib material directly to the compression stocking to thereby form a rib that is attached to the compression stocking and will in use overlie the dorsum of the patient's foot.

Philipp is silent to applying a silicone elastomer directly to the compression stocking, such that the silicone elastomer impregnates the compression stocking and forms a rib, curing the silicone elastomer to form a bond between the rib and the compression stocking.

However Einarsson discloses an orthotic tubular sleeve including a portion coated with silicone elasotmer bonded to the fabric material of the sleeve (col 1 ln 45-50) that is cured (col 4 ln 25-33).

It would have been obvious to one of ordinary skill in the art at the time of the invention to integrate the rib of the Philipp device by the known technique of bonding as taught by Einarsson in order to allow an alternative form of permanent attachment of the rib to the compression stocking.

Regarding claim 38, Philipp discloses an ankle-foot orthosis for resisting plantarflexion of a patient's foot (col. 2, lines 14-16), the orthosis comprising: an elastic

compression stocking (1) formed of contiguous first and second woven elastic tubular members(fig. 1), said second tubular member being set at an angle to the first tubular member to define, at least in use, an L-shaped cavity (FIG. 2) configured to accept and fit closely about the foot and ankle of the patient; a rib (7) formed directly on and thereby affixed (col. 4, lines 42-44) to a region of the stocking which overlies the dorsum of the patient's foot (col. 2, lines 30-35) in use, wherein the rib is configured and arranged to provide a resistance to plantarflexion (col.4, lines 39-42) that is appropriate for resisting the particular degree of plantarflexion experienced by the patient, and wherein the rib further comprises a pair of proximal wings(18) extending from the rib towards the back of the ankle of the patient (fig. 1), and a pair of distal wings (17) extending from the rib, in the region of the patient's metatarsal heads, towards the plantar aspect of the foot (fig. 1).

Although Philipp discloses the rib is made of an elastically yielding material, such as a plastic or steel (col. 4, lines 39-42), Philipp fails to disclose the rib is composed of a silicone elastomer.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize an elastically yielding material such as silicone elastomer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Further, utilization of a rib composed of silicone elastomer in order to stiffen or reinforce a support garment is a well known

quality known to one skill in the art, as evidenced by US patent 6,109,267 to Shaw et al. (see col. 5, lines 35-49).

Philipp fails to disclose the rib is bonded to a region of the compression stocking.

However Einarsson discloses an orthotic tubular sleeve including a portion coated with silicone elasotmer bonded to the fabric material of the sleeve (col 1 ln 45-50) that is cured (col 4 ln 25-33).

It would have been obvious to one of ordinary skill in the art at the time of the invention to integrate the rib of the Philipp device by the known technique of bonding as taught by Einarsson in order to allow an alternative form of permanent attachment of the rib to the compression stocking.

Further, the recitation -- said rib obtained by applying a silicone elstomer to the compression stocking so that the elastomer impregnates at least a portion of the compression stocking and forms, when cured, a bond between the rib and the compression stocking -- is treated as a product by process limitation. The determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985).A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art.

Philipp discloses the claimed invention except for the pair of distal wings extending from the rib around and partly underneath the foot and terminating underneath the foot. It would have been an obvious matter of design choice to design the wing in the manner stated above, since applicant has not disclosed that the portion of the wing being partly underneath the foot solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the distal wing design of Philipp.

With respect to claims 40 and 41, the recitation – rib is further obtained by applying the silicone elastomer to the portion of the compression stocking as one or more layers of silicone elastomer -- is treated as a product by process limitation. The determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985).A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art.

3. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Philipp (US 4559934) in view of Einarsson et al. (US 6,592,539) and further in view of Gardon-Mollard et al. (US 6430970).

Regarding claims 22, Philipp discloses an orthosis according wherein the elastic structure is woven to provide an elastic stretch (col. 4, lines 24-25), a stretch that increases the cross-sectional area of said generally L-shaped cavity.

Philipp fails to disclose that the elastic stretch is only in one direction and that the compressive force of the elastic structure is more or less than at least 5 mm Hg (approximately 670 Pascals).

However, Gardon-Mollard discloses a compressive orthosis (such as retention stockings) in which there is a greater elastic return force in the horizontal direction than in the vertical direction (col. 4, claim6), and that the compressive force of the elastic structure is more or less than at least 5 mm Hg (approximately 670 Pascals) (col. 2, lines 13-24).

To provide the device of Philipp with an elastic structure woven to provide an elastic stretch in one direction with a compressive force of more or less than at least 5 mm Hg would have been obvious to one of ordinary skill in the art, in view of the teachings of Gardon-Mollard, since all the claimed elements were known in the prior art and one skilled in the art could have combine the elements as claimed by known methods with no change in their respective functions. The combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention, i.e., one skilled in the art would have recognized that the material of Gardon-Mollard would allow the orthosis of Phillip to achieve unidirectional compression.

Response to Arguments

4. Applicant's arguments with respect to claim 19 that Philipp does not disclose, nor teach or suggest the flexible rib of silicone elastomer bonded to a region of the compression stocking has been considered but are moot in view of the new ground(s) of rejection. Applicant's position that plate member is constructed of a plastic, such as ORHTOLEN™ indicates the plate member is rigid or essentially rigid and therefor does not read on the claimed material property of "resilience" is respectfully not convincing. For clarity, the section of Philipp that applicant relies upon recites, "plate made of an elastically yielding material, for example, a plastic such as that known under the trade name "Ortholen", or steel." First, ORHTOLEN™ is merely one example material offered by Philipp. Second, it appears applicant has improperly disregarded Philipp's teaching of an elastically yielding material. Examiner maintains that an elastically yielding material explicitly reads on a material property of resilience. An elastically yielding material is entirely capable of achieving resilience, in the sense of a material having the ability to return to its original form or position after being bent, compressed, or stretched. Third, the claim recites "has a resilience that is appropriate for resisting the particular degree of platarflexion experienced by the patient". What is the appropriate resilience? Since applicant has not defined this resilience in the claim, the claim is interpreted as broadly as reasonably possible in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Robinson whose telephone number is (571) 270-3867. The examiner can normally be reached on Mon-Fri 9AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James M. Robinson/

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772